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PO BOX 33427 ST. PAUL, MN 55133-3427			KOKKINOS, NICHOLAS C		
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# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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# Application No. Applicant(s) 10/575,207 MATSUMURA ET AL. Office Action Summary Examiner Art Unit NICHOLAS KOKKINOS 1794 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 05 June 2009. 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 16-32 is/are pending in the application. 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 16-32 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received.

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (FTO/S5/08)
 Paper No(s)/Mail Date \_\_\_\_\_\_\_.

Attachment(s)

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

6) Other:

5 Notice of Informal Patent Application

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#### DETAILED ACTION

 The text of those sections of Title 35, U.S. Code not included in this section can be found in a prior Office Action.

#### Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: claim 22 recites a "unitary structure," but the specification does not explicitly discuss a "unitary structure," only alluding to the fastening element which has elements that are "unitarily combined" (page 7, line 4).

### Claim Rejections - 35 USC § 112

- The following is a quotation of the second paragraph of 35 U.S.C. 112:
   The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 4. Claims 20, 22, and 30-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 5. For claims 20 and 30-32, the addition of the word "type" extends the scope of the claims so as to render them indefinite since it is unclear what "type" is intended to convey. The addition of the word "type" to the otherwise definite expression renders the

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definite expression indefinite by extending its scope. Ex parte Copenhaver, 109 USPQ 118 (Bd. App. 1955).

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- 6. Claim 20 further recites the phrase "at a substantial center of said color chart."

  This phrase is indefinite because it is unclear what "a substantial center" is. The specification discusses this element of the claims (page 9, line 15), but only mentions one "substantial center," while the claim language makes clear that there could be more than one substantial center of the color chart. In addition, term "substantial center" is a relative term which renders the claim indefinite. The term "substantial center" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The corresponding lines in the specification do not provide any standard by which one can determine how substantially centered the window-type opening is on the color chart.
- 7. Claim 22 recites that the fastening member and the extensible member have a "unitary structure." The specification does not explicitly discuss a "unitary structure," only alluding to the fastening element which has elements that are "unitarily combined" (page 7, line 4); it is assumed that this forms the unitary structure in this example (see subsequent claims 23 and 24, for instance). However, the language of claim 23 indicates that the "unitary structure" is a separate feature entirely on the fastening element, not something formed by the fastening member and extensible member.
- Claim 31 recites that the cover cannot be "substantially seen through;" this is a relative term which renders the claim indefinite. The term "substantially seen through" is

not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Although the specification discusses the above limitation on page 9, lines 15-17, there is no indication of a standard where the claimed material "cannot be seen through."

## Claim Rejections - 35 USC § 103

- Claims 16-19 and 21-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 6,159,584 to Eaton et al. in view of USPN 6,142,968 to Pigg et al. in view of USPN 3,613679 to Bijou.
- Regarding claim 16, Eaton teaches a fastening element (fastening tab 6, Fig. 1, column 5, lines 19-37).
- 11. The limitation "for detachably fixing a disposable diaper" is deemed to be a statement with regard to the intended use and is not further limiting in so far as the structure of the product is concerned. In article claims, a claimed intended use must result in a *structural difference* between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. MPEP § 2111.02. In the case of the fastening elements of Eaton, both the disclosed pressure sensitive adhesive composition (*column 11*, *lines 66-67 and column 12*, *lines 1-14*) as well as the mechanical hook structure (*column 12*, *lines 15-26*) can attach, thus fixing, and detach from a diaper that may be disposed.

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12. Eaton also teaches that the fastening element is fitted to a tab (fastening tab material 10, Fig. 2), and that the fastening element comprises a fastening member (web layer 15, Fig. 2, column 6, lines 39-43). The fastening member has an extensible member (extensible zones 7, Fig. 2, column 6, lines 27-29). Eaton does not teach that the extensible member has an indicator printed on a face, and that the printed indicator changes with extension and contraction of the extensible member, and where the change in the printed indicator is capable of visually showing a degree of extension and contraction of the extensible member.

- 13. Bijou teaches an extensible member (elastic bandage 11, Figs. 4-15, column 2) that has a printed (column 1, lines 37-40) indicator (see the designs on the figures) on its face. The printed figures change with extension and contraction of the extensible member, and the change in the printed indicator is capable of visually showing a degree of extension and contraction of the extensible member.
- 14. Eaton teaches that for the elastic tabs on diapers, the forces of extension must be large enough to secure the diaper (engage the wearer), but not so great as to cause injury such as bruising or red marking (column 4, lines 30-33). Although Eaton suggests the solution of providing physical resistance (column 4, lines 1-12) to signal the user when the diaper is being fastened too tightly, it is clear that there are several drawbacks to this approach. First, Eaton acknowledges that the range of tensions that are injurious are significantly varied from patient to patient (column 4, lines 30-53). Second, though this is not explicitly taught, one of ordinary skill in the art would recognize that different caregivers have different levels of strength, which would affect

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the fastening of the tabs. Third, it would be recognized that reproducing the appropriate tension would be difficult without a visual guide as discussed by Bijou (column 1, lines 30-36).

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- 15. The disclosures of Eaton (diaper fasteners) and Bijou (bandages) are analogous art, as evidenced by Pigg, who teaches that both are directed at the same problem of precisely metering the amount of tension applied; elastic structures should have enough tension that they perform their intended function (column 1, lines 31-35), but not so much that they injure the wearer (column 1, lines 59-63). Pigg further indicates that the problem may be alleviated by marking the articles, such as in ways suggested by Bijou (column 2, line 1). It would have been obvious to one of ordinary skill in the art to mark the surfaces of the diaper tabs of Eaton as suggested by Bijou and Pigg with the printed markings taught by Bijou so that a precise, reproducible amount of tension could be applied by the caregiver when fastening a diaper to the wearer.
- 16. Regarding claim 17, Bijou teaches that the printed indicator comprises lines, patterns, symbols, illustrations, pictures (*Figs. 4-15*), and that the printed material can also comprise different colors so as to form a color chart or color code (*column 3, lines 33-47*).
- 17. It is further submitted that the remaining limitations of claim 17 (photographs, numerals) are deemed to be aesthetic design changes, because as claimed they do not impart any additional functionality over the prior art. Matters relating to omamentation only which have no mechanical function cannot be relied upon to patentably distinguish the claimed invention; substituting the lines, patterns, symbols, illustrations of Bijou with

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a photograph or numeral would not impart any additional functionality. *In re Seid*, 161 F.2d 229, 73 USPQ 431 (CCPA 1947).

- 18. Regarding claim 18, the printed indicator of Bijou is a print pattern (see above) and is printed at least partially to a surface of the extensible member. The print pattern is also deformable in accordance with extension and contraction of the extensible member (see for instance Figs. 7-15 of Bijou).
- 19. Regarding claim 19, applying the printed indicator of Bijou to the fastening element of Eaton et al. as above would at least partially print a color chart to the surface of the extensible member, because the printings of Bijou comprise color charts.

Further, the color charts of Bijou may comprise two or more colors (column 3, lines 40-

- 47). The colors change their dimension when tension is applied, as above, and do so regularly, or in a predictable fashion, in a predetermined direction (direction of tension).
- 20. Regarding claim 21, applying the printed indicator of Bijou to the surface of the extensible member of Eaton et al. would form the claimed structure, because in the embodiment of Eaton et al., the top sheet layer is porous (*slits 37, Figs. 5-7*). Application of the printed indicator to the sheet of Eaton et al. as above colors the top sheet. Subsequent expansion of the fastening element opens up the slits (*Fig. 6*). Because the surface of the porous layer has been colored, but the interior layers remain the same, perceived color will change as the sheet is expanded and contracted.
- Regarding claim 22, Eaton et al. teaches that the fastening member (web layer
   Fig. 2, column 6, lines 39-43) and the extensible member (extensible zones 7, Fig.

column 6, lines 27-29) have a unitary structure (Fig. 2, they are unified in one overall tab structure).

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- 22. Regarding claims 23 and 24, the fastening member (web layer 15) and the extensible member (extensible zones 7) are unified adjacent to each other (Fig. 2). Since the fastening member and extensible member are unified adjacent, or touching, one another, the structure is also such that the fastening member is unified with a part of the extensible member, again per Fig. 2.
- Regarding claim 25, the fastening member of Eaton et al. can be part of a mechanical fastener (hook fasteners, column 12, lines 15-26), as noted above.
- 24. Regarding claim 26, the fastening member of Eaton et al. can be an adhesive tape, because it is a substrate with an adhesive layer on it (column 11, lines 66-67 and column 12, lines 1-14), as above.
- 25. Regarding claims 27-30, the fastening element of Eaton et al. is fitted to an ear or tab of a diaper (*Fig. 1*). Eaton et al. also teaches an article (*disposable diaper*, *Fig. 1*) that comprises the above described fastening element, and said article is a diaper that is capable of being disposed of. Furthermore, the diaper as depicted by Eaton et al. is of the open type (it is fastened at the sides, presumably after being fitted to the wearer) (*Fig. 1*).
- Claims 20, 31, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 6,159,584 to Eaton et al. in view of USPN 6,142,968 to Pigg et

al., further in view of USPN 3,613,679 to Bijou as applied to claims 16-18 above, and further in view of USPN 6.075.178 to La Wilhelm et al.

- 27. Regarding claim 20, the structure of Eaton et al. in view of Pigg et al. in view of Bijou comprises the features of claim 19, but does not teach that the color chart is covered with a cover having a window-type opening at the substantial center of the color chart.
- 28. Such a structure has a distinct drawback, namely, that it is often difficult to assess when a desired degree of extension has been achieved (*Pigg et al., column 2, lines 9-11*), due to things like the different limbs and bodies of the wearers and different users applying the article (*column 2, lines 12-18*). Failure to determine the desired degree of extension leads to discomfort to the wearer, whose diaper may be improperly fitted, and who may be disturbed by the user who, unsure of diaper tension, must reapply the tabs to ensure proper fit.
- 29. La Wilhelm et al. teaches that for users of articles such as diapers, it is desirable to assess the condition of the diaper without disturbing its wearer (*infant, column 1, lines* 27-29), and suggests that the best way to definitely indicate to the user the condition of the diaper is to provide a plurality of translucent windows (*column 2, lines 2-9*) over a contrast layer (*column 2, lines 37-45*).
- 30. Although La Wilhelm et al. addresses this problem from the standpoint of wetness, the same arguments apply to the fit of the diaper; it is desirable for the user to assess both the fit and wetness of a diaper without disturbing the infant. The contrast layer of La Wilhelm et al. with regard to wetness is analogous to the printed color chart

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of Bijou with regard to degree of extension, as each is a visual indicator of a diaper condition. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention add the windowed cover sheet of La Wilhelm et al. on top of the color chart taught by Bijou. One of ordinary skill in the art would expect such a modification to be successful because the means of indication (*color change*) is the same for both wetness in La Wilhelm et al. and degree of extension in Bijou. Finally, one of ordinary skill in the art would place the window-type opening at the substantial center of the color chart as part of the above modification, because otherwise the indicator would be inoperable (*the user would be unable to view the color chart*).

- 31. For claim 31, the cover of La Wilhelm is structured such that it is a single piece of polymer sheet layer, where the "windows" are formed by selected thermal treatment of the polymer sheet layer (column 12, lines 1-6). The windows become translucent, which means that before, they were not (the thermal treatment briefly melts the polymer and makes it translucent, forming the windows). This means that areas not treated remain opaque (for instance, if they were stretched, column 13, lines 43-54), thus forming the structure of claim 31, wherein the cover cannot be substantially seen through, and the color regions can be observed through the window opening. This is best depicted by Fig. 7 of La Wilhelm.
- 32. For claim 32, La Wilhelm teaches that the cover with windows may be formed of a variety of different polymers (*column 12*, *lines 14-49*), and that the polymers may be stretched up to 4.7 times their original dimension during manufacturing (*column 12*, *lines 40-49*). Although not explicitly mentioned, the polymers would also be able to

contract if they aren't stretched too much past the point of plastic deformation, because such elasticity is required for the windowed backsheet of La Wilhelm to be comfortable to the wearer, who is likely to move around while wearing the article. These features would allow the window opening of La Wilhelm to extend and contract in accordance with the extension and contraction of the extensible member.

## Response to Arguments

- Receipt of the response to the previous Office Action, dated 5 June 2009, is acknowledged.
- 34. The objection to the specification over the reference character "7" is withdrawn in light of the submitted amendments.
- 35. The objection to the abstract over legal phraseology and grammatical errors is withdrawn in light of the submitted amendments.
- 36. It is confirmed that per the telephone conversation on 4 June 2009, there is no objection to the drawings.
- 37. Applicant's arguments with respect to the rejections under 35 U.S.C. 103 have been fully considered and are persuasive; the rejections have been withdrawn.
  However, new grounds of rejection have been advanced.
- 38. Applicant argues several points that merit further discussion. The first is that Pigg teaches away from the marking techniques of Bijou. However, the cited lines do not support this assertion. Pigg cites Bijou as an example of the prior art, and continues by stating "For example, it is known to provide compression bandages having markings."

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which appear as squares when a planar bandage is stretched to a desired degree and which in an unstretched state appear as narrow rectangles. However, these bandages suffer from the disadvantage that it is often difficult to assess when a desired degree of extension has been achieved" (column 2, lines 5-11). This is not a "teaching away" from the disclosure of Bijou, and only amounts to a teaching away from markings which appear solely as squares or rectangles. Bijou only teaches such markings in Figs. 1-3, while the other embodiments use more complex geometrical shapes to mitigate the problems of the squares (Figs. 4-15).

- 39. The second point is applicant's contention that given that Eaton alone teaches a signal to the user to cease pulling on the tab, that the elastic performance from one user to the next is predictable, and that consequently the "Useful Stretch Ratio" solves the problem of wearer injury (column 4, lines 1-12 and lines 54-67 of Eaton). Applicant concludes that one of ordinary skill in the art would not look to a secondary reference to solve a problem already solved by the primary reference.
- 40. However, such a statement cannot be supported by reading Eaton in the context of the prior art as whole. For example, Eaton discusses a fairly wide range of suitable elastic recovery forces which govern the occurrence of bruising and injury (an entire order of magnitude, column 4, lines 30-41), and notes that there is considerable variability when the complexion of the wearer is considered (adults versus fair skinned adults and infants). Such a disclaimer serves to indicate that a purely force-based approach to preventing wearer injury may not provide the accuracy and reproducibility required to care for differing patient groups. Also, though not mentioned, it can be

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plainly shown that different caregivers have different levels of physical strength; what feels like high resistance for one caregiver might feel like low resistance to another.

#### Conclusion

- 41. Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICHOLAS KOKKINOS whose telephone number is (571) 270-7384. The examiner can normally be reached on Monday-Thursday 9am-5pm.
- 42. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on (571) 272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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43. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

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/NK/ 22 September 2009

/Callie E. Shosho/ Supervisory Patent Examiner, Art Unit 1794